

# EXHIBIT B

Kimberly Kenton, M.D.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., )  
PELVIC REPAIR SYSTEM )  
PRODUCTS LIABILITY ) Master File No.  
LITIGATION ) 2:12-MD-02327  
 ) MDL 2327  
 )  
 )  
 ) JOSEPH R. GOODWIN  
 ) U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO: )  
THE CASES LISTED BELOW )  
 )  
 )

Mullins, et al. V. ) 2:12-cv-02952  
Ethicon, Inc., et al. )  
 )

Sprout, et al. V. ) 2:12-cv-07924  
Ethicon, Inc., et al. )  
 )

Iquinto v. Ethicon, Inc., ) 2:12-cv-09765  
et al. )  
 )

Daniel, et al. V. ) 2:13-cv-02565  
Ethicon, Inc., et al. )  
 )

Dillon, et al. V. ) 2:13-cv-02919  
Ethicon, Inc., et al. )  
 )

Webb, et al. V. Ethicon, ) 2:13-cv-04517  
Inc., et al. )  
 )

Martinez v. Ethicon, ) 2:13-cv-04730  
Inc., et al. )  
 )

McIntyre, et al. V. ) 2:13-cv-07283  
Ethicon, Inc., et al. )  
 )

VIDEOTAPED DEPOSITION OF KIMBERLY KENTON, Ph.D.  
Thursday, February 18, 2016, 5:48 p.m.

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1	Oxley v. Ethicon, Inc.,	)	2:13-cv-10150
	et al.	)	
2		)	
	Atkins, et al. V.	)	2:13-cv-11022
3	Ethicon, Inc., et al.	)	
		)	
4	Garcia v. Ethicon, Inc.,	)	2:13-cv-14355
	et al.	)	
5		)	
	Lowe v. Ethicon, Inc., et	)	2:13-cv-14718
6	al.	)	
		)	
7	Dameron, et al. V.	)	2:13-cv-14799
	Ethicon, Inc., et al.	)	
8		)	
	Vanbuskir, et al., v.	)	2:13-cv-16183
9	Ethicon, Inc., et al.	)	
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10	Mullens, et al. V.	)	2:13-cv-16564
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11		)	
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12	Ethicon, Inc., et al.	)	
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13	Javins, et al., v.	)	2:13-cv-18479
	Ethicon, Inc., et al.	)	
14		)	
	Barr, et al. V. Ethicon,	)	2:13-cv-22606
15	Inc., et al.	)	
		)	
16	Lambert v. Ethicon, Inc.,	)	2:13-cv-24393
	et al.	)	
17		)	
	Cook v. Ethicon, Inc., et	)	2:13-cv-29260
18	al.	)	
		)	
19	Stevens v. Ethicon, Inc.,	)	2:13-cv-29918
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20		)	
	Harmon v. Ethicon, Inc.,	)	2:13-cv-31818
21	et al.	)	
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1	Snodgrass v. Ethicon,	)	2:13-cv-31881
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3	Miller v. Ethicon, et al.	)	2:13-cv-32627
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4	Matney, et al. V.	)	2:14-cv-09195
	Ethicon, Inc., et al.	)	
5		)	
	Jones, et al. V. Ethicon,	)	2:14-cv-09517
6	Inc., et al.	)	
		)	
7	Humbert v. Ethicon, Inc.,	)	2:14-cv-10640
	et al.	)	
8		)	
	Gillum, et al. V.	)	2:14-cv-12756
9	Ethicon, Inc., et al.	)	
		)	
10	Whisner, et al. V.	)	2:14-cv-13023
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11		)	
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12	et al.	)	
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13	Schepleng v. Ethicon,	)	2:14-cv-16061
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14		)	
	Tyler, et al. V. Ethicon,	)	2:14-cv-19110
15	Inc., et al.	)	
		)	
16	Kelly, et al. V. Ethicon,	)	2:14-cv-22079
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17		)	
	Lundell v. Ethicon, Inc.,	)	2:14-cv-24911
18	et al.	)	
		)	
19	Cheshire, et al. V.	)	2:14-cv-24999
	Ethicon, Inc., et al.	)	
20		)	
	Burgoyne, et al. V.	)	2:14-cv-28620
21	Ethicon, Inc., et al.	)	
		)	
22	Bennett, et al. V.	)	2:14-cv-29624
	Ethicon, Inc., et al.	)	
23		)	
24	VIDEOTAPED DEPOSITION OF KIMBERLY KENTON, Ph.D. Thursday, February 18, 2016, 5:48 p.m.		

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1           A.     Yes.

2           Q.     -- as an academic physician, is that  
3     right?

4           A.     Yes.

5           Q.     And yet those were provided to you by  
6     counsel, correct?

7           A.     Correct.

8           Q.     And does this reliance list contain all  
9     of the Ethicon documents that you reviewed in  
10    connection with your report?

11          A.     Yes.

12          Q.     Okay. You started using the TVT in the  
13    mid-2000s, correct?

14          A.     That's correct.

15          Q.     What year did you start using it?

16          A.     Hard to say exactly, but probably around  
17    2004-2005.

18          Q.     Okay. And in your -- how did you treat  
19    SUI surgically before you started using the TVT?

20          A.     I am a fellowship-trained  
21    urogynecologist for female pelvic medicine  
22    reconstructive surgery who did a combination of  
23    both bladder neck fascial slings as well as Burch  
24    colposuspensions in addition to less invasive

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1 procedures like urethral bulking, an occasional  
2 Kelly plication in patients who had very mild  
3 stress incontinence and were older.

4 Q. How many fascial slings have you done as  
5 a --

6 A. Hundreds.

7 Q. -- fellowship-trained urogynecologist in  
8 female pelvic health and reconstructive surgery?

9 A. Hundreds.

10 Q. How many Burch procedures have you done  
11 in your time?

12 A. Hundreds, perhaps more.

13 Q. When's the last time you did a fascial  
14 sling?

15 A. Probably three months ago.

16 Q. And in 2015 can you estimate for me  
17 about how many fascial slings you performed?

18 A. Probably six.

19 Q. And when's the last time you did a Burch  
20 procedure?

21 A. July of 2015.

22 Q. Okay. And can you estimate for me how  
23 many Burch procedures you did in 2015?

24 A. Five.

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1 Q. And how many TVT procedures did you do  
2 in 2015 approximately?

3 A. I'm trying to do like math, which is not  
4 my strong suit. Probably like 150, 200.

5 Q. Do you still only see patients one day a  
6 week?

7 A. One and a half days a week.

8 Q. And what days do you see patients?

9 A. I see patients on Tuesdays and Wednesday  
10 mornings and then I operate a day and a half a week  
11 as well.

12 Q. Okay. And what days do you operate?

13 A. Mondays and Wednesday afternoon.

14 Q. And then what do you do on Thursday and  
15 Friday?

16 A. Research, administration, national work.

17 Q. What type of research do you do?

18 A. Mostly clinical outcomes research and  
19 comparative effectiveness trials. We do have some  
20 translational programs going on the urinary  
21 microbiome.

22 Q. Do you mind keeping your voice up a  
23 little? I'm having a little bit of a hard time  
24 hearing you.

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1 Q. It's okay to say you don't know if you  
2 don't know. I just --

3 MR. SNELL: If you don't understand her  
4 question, tell her that again and maybe she can try  
5 to rephrase it or formulate it so you can  
6 understand it.

7 She's already told you that three times.

8 BY THE WITNESS:

9 A. Yeah, I mean, I need more clarification.  
10 I have said that a couple times.

11 BY MS. FITZPATRICK:

12 Q. You understand that there is different  
13 types of polypropylene, but you don't understand  
14 the question when I say what type of polypropylene  
15 is the Ethicon medical device? I can leave it at  
16 that, that you don't understand the question.

17 A. Okay.

18 Q. That's good enough.

19 A. That's good enough.

20 Q. What antioxidants are added to the  
21 polypropylene that is used in the Ethicon TVT?

22 A. As I indicated before, that is not the  
23 level of expertise I have.

24 Q. Who makes the polypropylene that is used

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1 in the Ethicon TVT?

2 A. I have no idea.

3 Q. Do you know whether the polypropylene  
4 that is used in the Ethicon TVT is the same as the  
5 polypropylene that is used in the Boston Scientific  
6 Advantage?

7 A. I do not.

8 Q. Do you know whether the antioxidants  
9 that are used in the TVT -- do you know whether  
10 antioxidants are used in the TVT polypropylene?

11 A. As I said, I do not know that level.

12 Q. Do you know whether --

13 A. Because I don't think it's clinically  
14 relevant as evidenced by the multitude of  
15 peer-reviewed literature.

16 Q. Do you believe that the multitude of  
17 peer-reviewed literature establishes that all  
18 polypropylene midurethral slings perform in the  
19 same way?

20 A. I do not think that they -- it  
21 establishes they all perform in the same way.

22 Q. Do you think that the peer-reviewed  
23 literature establishes that different polypropylene  
24 midurethral slings -- let me change this question a

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1           A.     No, I don't disagree with that answer.

2           Q.     So, you do understand and you do believe  
3     that there is a difference between product design  
4     and clinical outcomes?

5           A.     I mean, they're -- I mean, designing a  
6     product and like analyzing an outcome data, of  
7     course that's different.

8           Q.     Okay. And your expertise here is as a  
9     clinician and a researcher looking at the clinical  
10    outcomes associated with the TVT device, correct?

11          MR. SNELL: Objection.

12    BY THE WITNESS:

13          A.     No, I actually think that I am a surgeon  
14    scientist who, as I've said before, has been  
15    involved in design.

16    BY MS. FITZPATRICK:

17          Q.     Okay. Have you been involved in the  
18    design of the -- has Ethicon ever hired you or  
19    retained you in association with the design of any  
20    of its pelvic mesh products?

21          A.     They haven't and I -- as I indicated  
22    earlier, I have never been hired or allowed myself  
23    to be hired formally by any industry or design  
24    company.

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1           A.     I believe --

2           MR. SNELL:   Form, scope.   Go ahead.

3   BY THE WITNESS:

4           A.     While they've never been directly  
5   compared, I think that Gore-Tex sutures -- I mean,  
6   it depends on what you're using it for, of course.

7                   At the time of sacral colpopexy,  
8   probably have a slightly higher suture extrusion or  
9   erosion rate into the vagina but those are  
10   typically managed with a quick snip in the office.  
11   The suture comes out and you can move on.   So, I  
12   don't think it's a clinically relevant difference.

13   BY MS. FITZPATRICK:

14           Q.     Okay.

15           MS. FITZPATRICK:   Are we at 11?

16           THE REPORTER:   11 is next.

17                   (WHEREUPON, a certain document was  
18                   marked as Kenton Deposition Exhibit  
19                   No. 11:   Article by Blaivas, et  
20                   al., "Safety considerations for  
21                   synthetic sling surgery.")

22   BY MS. FITZPATRICK:

23           Q.     Dr. Kenton, I've given you an article  
24   entitled "Safety Considerations for Synthetic Sling

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1 Surgery" that was published in 2015.

2 Have you seen this article before?

3 A. I've seen it.

4 Q. Have you read it?

5 A. I have not.

6 Q. Okay. And are you familiar with any of  
7 the authors?

8 A. I know Dr. Blaivas.

9 Q. Is there anyone else here that you know?

10 A. No.

11 Q. How do you know Dr. Blaivas?

12 A. He used to be the editor for one of our  
13 journals. I've taught in a course with him before.

14 Q. Now, you've offered opinions here on  
15 safety issues concerning the TVT sling, correct?

16 A. Correct.

17 Q. Why haven't you read this article?

18 A. This is essentially a book chapter that  
19 is just one, a group of people reviewing it and not  
20 in a systematic format and formulating their  
21 opinions.

22 Q. Okay.

23 A. I think that maybe ten years ago when I  
24 was a fellow I would have read something like this.

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1           Q.     -- specific articles that compare the  
2     TVT to the autologous fascial sling, correct?

3           A.     Correct.

4           Q.     And in these Schimpf -- in the five  
5     articles that or the five RCTs that Schimpf reports  
6     on, the efficacy between the pubovaginal sling and  
7     the polypropylene midurethral sling is  
8     approximately the same, correct?

9           MR. SNELL: Foundation.

10          BY THE WITNESS:

11          A.     Depends on how you define "efficacy."  
12     The efficacy of as far as subjective outcomes are  
13     better with the midurethral sling.

14          BY MS. FITZPATRICK:

15          Q.     I'm sorry. I just didn't hear you  
16     again.

17          A.     Subjective outcomes, they conclude, are  
18     superior with midurethral sling to pubovaginal  
19     sling.

20                   Efficacy is a tricky question in  
21     quality-of-life outcomes.

22          Q.     Okay. So -- give me one second on this  
23     so I can get these organized.

24          A.     I would also like to mention that if

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1 we're going to talk about a very well-done,  
2 systematic controlled trial having low quality of  
3 evidence, the Blaivas article --

4 Q. I'm so sorry. I just cannot hear you.

5 A. If we want to focus on the quality of  
6 the evidence of the trials and the systematic  
7 review being low, we can -- the Blaivas article  
8 doesn't even hit the -- like doesn't even hit the  
9 radar. So, if these are low --

10 Q. I don't understand what you mean  
11 "doesn't hit the radar."

12 A. Like there is no --

13 Q. It's not a randomized controlled trial,  
14 correct?

15 A. Well, and it's -- it's based on lower  
16 evidence than randomized controlled trial. These  
17 data wouldn't even be ranked.

18 Q. You think the 397 articles and studies  
19 that Dr. Blaivas has cited are data that wouldn't  
20 even be ranked and are not reliable, is that what  
21 your testimony is?

22 A. The majority of those articles are not  
23 well-done, prospective, randomized controlled  
24 trials or prospective data. They wouldn't even be

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1 included in the study design of a systematic  
2 analysis. That's correct.

3 Q. Should we go through the 397 so you can  
4 tell me what you think is authoritative or not?

5 I'm not really understanding. I thought  
6 you brought up Schimpf. We're going through -- I  
7 quote a section from this. But if you want to go  
8 back to Blaivas, we can talk about that.

9 MR. SNELL: It's your time, counsel. You can  
10 do what you want. If you want to ask her about  
11 each of the 300 studies, feel free to.

12 BY MS. FITZPATRICK:

13 Q. You haven't even read this article. How  
14 do you know what the 397 cites in the article are  
15 to if you've never even read it?

16 A. As we have talked about with the levels  
17 of evidence, that is an opinion piece where someone  
18 has just taken a bunch. There is rules on how you  
19 do a systematic review.

20 Q. Was anyone claiming that this was a  
21 systematic review?

22 A. No, but you want to talk about the  
23 quality of the data here. I think we need to talk  
24 about the quality of the data there.

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1           Q.     Okay. The data that Dr. Blaivas cites  
2     in here are reflected in his 397 footnotes,  
3     correct?

4           A.     Correct.

5           Q.     And before you sat down today you've  
6     never actually read this article, correct?

7           A.     That's correct.

8           Q.     Which means you haven't read the 397  
9     footnotes, so you don't know what articles are  
10    actually cited in Dr. Blaivas' paper, correct?

11          A.     I know the amount of high-quality data,  
12    the highest quality data in our field, and there is  
13    nowhere near 300 high-quality, sadly, outcome  
14    papers or safety papers on any incontinence  
15    procedures.

16          Q.     Okay. And, in fact, how many what you  
17    call high-quality data in your field exists  
18    concerning the safety of the TVT retropubic  
19    mechanically-cut sling?

20          A.     We can go through this. These are the  
21    highest quality data we have.

22          Q.     Okay. So, when you say -- but you'll  
23    agree with me --

24          A.     And I would say --

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1           Q.     -- you don't actually know what  
2     Doctor --

3           A.     The second level of data that I would  
4     use, it's not going to be included in a systematic  
5     review. If you want to do safety and outcome are  
6     some of the large database studies where they  
7     follow 60,000 women, not case series of one  
8     surgeon's like 69 patients.

9           Q.     Okay. Doctor, you don't know what's in  
10    the 397 footnotes so you wouldn't possibly sit  
11    here --

12          A.     We looked at a couple of them. I am  
13    happy --

14          Q.     We looked at two of them.

15          A.     I am happy to go through them.

16          Q.     Well, you're supposedly an expert in  
17    your field. You didn't feel it necessary to read  
18    this article. You've never looked at the  
19    footnotes.

20                 You will agree with me, please, that you  
21    cannot comment on the literature that's cited in  
22    Dr. Blaivas' paper if you don't even know what that  
23    literature is, right?

24          MR. SNELL: Objection; form.

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1 BY THE WITNESS:

2 A. Yeah, I disagree with that but...

3 BY MS. FITZPATRICK:

4 Q. You can. You can comment on the quality  
5 of the literature even though you haven't looked at  
6 this, you haven't read it and you don't know what's  
7 in these footnotes?

8 A. We just spent probably 15 minutes going  
9 through some of the paper -- some of the --

10 Q. We went through two --

11 A. Read the paper.

12 Q. We went through two of 397.

13 A. No, we went through the -- read several  
14 paragraphs of how he came upon those conclusions.

15 Q. I'm talking about the data that's in the  
16 390 -- you've never -- let's do it this way.

17 Turn to page 22 of Dr. Blaivas'.

18 A. I'm not going to go --

19 Q. You've never read this page before, have  
20 you?

21 A. I'm not going to go through --

22 Q. Have you ever read this page before,  
23 Doctor?

24 A. The references, his references?

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1 Q. Yes.

2 A. I have not read that particular page of  
3 his references.

4 Q. Have you read page 23? Have you read  
5 that reference?

6 A. Actually we did look at page 22.

7 Q. Have you read this whole page, Doctor?

8 A. I have skimmed that page.

9 Q. Have you read this page?

10 A. Yes.

11 Q. Do you know what these 51 articles are?

12 A. I don't know all of them. I know a  
13 great deal of them.

14 Q. Doctor, you never looked at it before  
15 you sat down.

16 MR. SNELL: Objection; form.

17 BY MS. FITZPATRICK:

18 Q. You've never looked at this. You have  
19 never looked at this paper and yet you are going to  
20 tell a jury here that you've read through these 51  
21 and you know enough of what these are and are not?

22 A. I do. I -- as I've indicated earlier in  
23 my testimony, I spent a great deal of time going  
24 through the peer-reviewed literature. I am

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1 familiar with many of these papers. I can  
2 eyeball --

3 Q. You don't know what he cites?

4 MR. SNELL: Don't interrupt. She is answering  
5 your question.

6 BY THE WITNESS:

7 A. And I can eyeball many of these studies  
8 and know that I have seen them in the past,  
9 probably 15 years ago. I would have actually read  
10 some of them. And they are like antiquated and  
11 not -- they have been replaced by higher quality  
12 data.

13 BY MS. FITZPATRICK:

14 Q. Okay. Is there any high-quality data  
15 that's referenced in Dr. Blaivas' 397 footnotes?

16 A. Sure. There is the -- there is a  
17 reference for -- I just saw it. The -- one of --  
18 the TOMUS 24-month outcome paper is referenced  
19 there.

20 Q. What's missing from this that you  
21 consider to be high-quality data that Dr. Blaivas  
22 should have relied on?

23 A. I think that it's --

24 Q. What data is missing from here?

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1           A.     I can't tell go through here and tell  
2     you what's missing, but I can --

3           Q.     That's because you haven't read it,  
4     right?

5           A.     I can tell you what's included. There's  
6     reasons that many of these papers aren't included  
7     in a systematic review, which we have established  
8     is -- or meta-analyses, is the highest level of  
9     evidence we have.

10          Q.     So, your complaint with Dr. Blaivas'  
11     paper is that he cites -- he provides too much  
12     information, he cites too many papers?

13          A.     He provides --

14          Q.     Not that he hasn't cited relevant ones.  
15     Correct?

16          MR. SNELL: Form.

17     BY THE WITNESS:

18          A.     Well, I think you can by -- I think he  
19     cites relevant and irrelevant and doesn't  
20     effectively weight them appropriately.

21     BY MS. FITZPATRICK:

22          Q.     Can I ask you, how do you know that if  
23     you haven't read the paper?

24          A.     Because that is what a review article

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1 does. It's the nature of the document.

2 Q. How do you know what he's weighted or he  
3 hasn't if you've never read the paper?

4 A. Well, first of all, we have read parts  
5 of it together.

6 Q. Doctor, please tell me that when a  
7 patient comes in and you tell her that you're up to  
8 date on the medical literature, that you keep on  
9 top of it, that the way that you do it is something  
10 a little better than looking at random sentences in  
11 an article and skimming one page of a reference  
12 list. That's not how you do research, is it?

13 MR. SNELL: Objection; form.

14 BY THE WITNESS:

15 A. This is not a research article.

16 BY MS. FITZPATRICK:

17 Q. You --

18 A. This is --

19 Q. This is not how you do research.

20 A. This is essentially a book chapter.  
21 This is an opinion piece.

22 Q. This is not how you do research. Is  
23 that -- please answer my question.

24 MR. SNELL: Objection; form. It's been asked

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1 and answered.

2 BY MS. FITZPATRICK:

3 Q. It's --

4 A. This is not --

5 MR. SNELL: It's been asked and answered.

6 BY MS. FITZPATRICK:

7 Q. Frankly --

8 A. It's not how I do research because it's  
9 not research. No one can do research that way.

10 Q. It is absolutely mind-boggling to me  
11 that you would sit here and offer criticisms of an  
12 article and make assumptions about an article that  
13 you haven't even read.

14 MR. SNELL: Objection. That's not a question.

15 BY MS. FITZPATRICK:

16 Q. I'm wondering is that how you do  
17 research? Do you make assumptions about things  
18 that you haven't even read?

19 MR. SNELL: Same objection. Now  
20 argumentative.

21 THE WITNESS: You think?

22 BY THE WITNESS:

23 A. So, as I said, that is not research and  
24 there are different -- I feel like we have gone

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1 through this numerous times, that there are levels  
2 of evidence and the highest -- I'm not going to  
3 make my decisions based upon essentially a book  
4 chapter, which is not even peer-reviewed. I mean,  
5 it probably has some peer review.

6 Q. Is it your -- is it actually your  
7 testimony you're making an assumption this is not a  
8 peer-reviewed article?

9 A. No. I did -- I actually -- did you  
10 listen to what I said?

11 Q. Yes.

12 A. I actually said it is peer-reviewed.

13 Q. Which is not -- "essentially a book  
14 chapter, which is not even peer-reviewed."

15 A. And then what did I say right after  
16 that?

17 Q. "Probably has some peer review."

18 Do you know whether this is  
19 peer-reviewed or not? Sitting here today do you  
20 know whether this is peer-reviewed or not?

21 A. Urology a is peer-reviewed journal.

22 Q. Okay. So, this is a peer-reviewed  
23 article, correct?

24 A. That's correct.

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1           Q.     And it does cite Level 1 evidence,  
2     correct?

3           A.     And it cites a whole lot of Level 3 case  
4     series from a single site.

5           Q.     Is there any Level 1 evidence that you  
6     believe is missing from this?

7           A.     I couldn't answer that question.

8           Q.     You can't answer that question because  
9     you haven't read it, right?

10          A.     Correct.

11          Q.     Okay. Is it possible that you don't  
12     like this article because it's written by someone  
13     who testifies on behalf of injured women? Is that  
14     part of the reason that you just decided that  
15     you're going to discount anything that's said in  
16     here and make assumptions that are not based on  
17     fact?

18          MR. SNELL: Form, foundation.

19     BY THE WITNESS:

20          A.     Absolutely not.

21          MR. SNELL: Actually misstates her opinion.

22     BY THE WITNESS:

23          A.     I can unequivocally say that's not the  
24     case.

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1 BY MS. FITZPATRICK:

2 Q. I just --

3 A. The same article could be written in  
4 support of TVT or midurethral sling and I wouldn't  
5 be citing it and supporting it because there is  
6 higher levels of data and better papers that  
7 compile the data than this. It's got nothing to do  
8 with what it says. It's the process in which these  
9 data are compiled.

10 Q. Okay.

11 MS. FITZPATRICK: Let's mark this as  
12 Exhibit 12.

13 (WHEREUPON, a certain document was  
14 marked as Kenton Deposition Exhibit  
15 No. 12: AUGS-SUFU "Position  
16 Statement on Mesh Midurethral  
17 Slings for Stress Urinary  
18 Incontinence.")

19 BY MS. FITZPATRICK:

20 Q. Have you seen this before, Dr. Kenton?

21 A. The AUGS position, SUFU position  
22 statement, I have.

23 Q. This is a "Position Statement on Mesh  
24 Midurethral Slings for Stress Urinary

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1 Incontinence," correct?

2 A. It is.

3 Q. And if you look at the back, it's got 14  
4 references, correct?

5 A. Correct.

6 Q. Do you consider -- you don't consider  
7 Dr. Blaivas' peer-reviewed article to be reliable  
8 or to inform your opinions. Do you consider the  
9 AUGS position statement to be reliable and inform  
10 your opinions?

11 A. I think that the AUGS position statement  
12 is reliable. It is not what drives my opinions.

13 Q. Okay. Why is the AUGS-SUFU position  
14 statement reliable but Dr. Blaivas' peer-reviewed  
15 publication, "Safety Considerations for Synthetic  
16 Sling Surgery," not reliable?

17 A. I think that if you look at the things  
18 that are being cited here, they're relying -- the  
19 AUGS position statement is relying on primarily  
20 RCTs, a systematic review, surgery versus  
21 physiotherapy for stress incontinence, randomized  
22 controlled trial in the New England Journal of  
23 Medicine, a Cochrane review and so -- another  
24 Cochrane review, another systematic analysis,

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1 another RCT.

2 So, the level of data that they relied  
3 on to make this position statement, they didn't  
4 overstretch, they didn't comment on things that  
5 don't have high-quality data.

6 Q. So, you know or do you know that what's  
7 cited in the position statement is also cited in  
8 Dr. Blaivas' article? Do you know that or not?

9 A. I do.

10 Q. Okay. So, the AUGS position statement  
11 and Dr. Blaivas rely on these same literature that  
12 you consider to be reliable, correct?

13 MR. SNELL: Form, foundation.

14 BY THE WITNESS:

15 A. As I stated, it's not what is -- it's  
16 not what is included. It's what it -- excluded.  
17 It's what's included in here.

18 BY MS. FITZPATRICK:

19 Q. Now, you're not testifying --

20 A. Much of -- much of the things, like the  
21 complication data in here, are based on case  
22 reports and small case series.

23 Q. How do you know that if you haven't read  
24 it?

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1           A.     Because I'm familiar with the  
2     literature. When you're looking at like the  
3     abscesses from TOTs, those are not. Those are  
4     small. Those are case reports and case series.

5           Q.     Let me ask you. Just leave that there.  
6                   What did Dr. Blaivas cite? What  
7     articles -- you said, just told me that you're  
8     looking at abscesses from TVT. Those are case  
9     reports and case series. What is it? What did he  
10    cite?

11          MR. SNELL: Objection; misstates. She said  
12    TVT-O. I think you ought to fix your question.  
13    BY MS. FITZPATRICK:

14          Q.     What did he cite?

15          A.     I can't tell you the papers, but I know  
16    the literature. There is --

17          Q.     If you don't know what he cited, how can  
18    you make that --

19          A.     Because I know --

20          Q.     -- assumption?

21          A.     Because I know what's out there to cite.  
22    It's not a huge body of literature. I read it.

23          Q.     Did it ever occur to you to maybe take a  
24    look at this article, even if you disagree with

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1 Dr. Blaivas' assumptions, and maybe look at the  
2 backup data to see if there is anything there that  
3 you didn't know before?

4 A. So, I guess I don't -- I didn't feel --  
5 I don't feel the need to read a review article when  
6 I can read the data and interpret it and make my  
7 own assumptions.

8 Q. You don't -- my point is, Dr. Kenton,  
9 you don't know what data he relied on. Why is it  
10 so hard to say, "Yes, I don't know what data he  
11 relied on because I didn't read the article"?

12 MR. SNELL: Because she's answered your  
13 question three times. Objection; asked and  
14 answered numerous times.

15 BY MS. FITZPATRICK:

16 Q. So, you rely on AUGS and SUFU. Do you  
17 think this AUGS-SUFU statement is a systematic or  
18 scientific review of literature in any way?

19 A. I said that it was not. It was based on  
20 systematic reviews and randomized controlled  
21 trials.

22 Q. Okay. And when you look at the  
23 "Midurethral Sling Task Force" on page 3 of the  
24 AUGS-SUFU.

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1 your position? How do you reconcile that?

2 A. I can --

3 MR. SNELL: Hold on. Objection; compound and  
4 also misstates her opinion and this has been asked  
5 and answered about four times now. It's also  
6 argumentative. Go ahead.

7 BY THE WITNESS:

8 A. Can you repeat the question.

9 BY MS. FITZPATRICK:

10 Q. Sure. Happy to do that.

11 You've testified -- I'll break it down  
12 into a whole bunch of little questions.

13 You've testified that you believe that  
14 the AUGS and SUFU statement are reliable, correct?

15 A. Yes.

16 Q. You've testified that you don't believe  
17 that Dr. Blaivas' article is reliable, correct?

18 A. I didn't say it wasn't reliable. I said  
19 it's not how I -- it's not a document that I would  
20 use to make my decisions. I didn't use this  
21 document to make my decisions either for the  
22 record.

23 Q. Okay. So, then let me ask you this: Is  
24 Dr. Blaivas' article in a peer-reviewed publication

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1 reliable?

2           **A.**     I guess we should get down to like --  
3 you're going to be annoyed about "reliable." What  
4 do you mean reliable? It's a reliable  
5 interpretation of -- it's reliable outcome of his  
6 interpretation of the literature, much of which is  
7 his.

8           **Q.**     Dr. Kenton, can you explain something to  
9 me. When I asked you if AUGS-SUFU is reliable, you  
10 said yes unequivocally. When I asked you the next  
11 question, is Dr. Blaivas reliable, you can't give  
12 me a yes or no answer.

13                   Did your definition of "reliable" change  
14 or your understanding of the word change between  
15 those two questions?

16           **A.**     I feel that I've answered this question  
17 on numerous -- numerous times. This paper --

18           **Q.**     Is AUGS-SUFU reliable?

19           **A.**     This paper is relying on mostly Level 1  
20 evidence, systematic reviews, meta-analyses or  
21 randomized controlled trials. They don't overstate  
22 their position. They take the data and what we  
23 know and they make comments.

24                   This also includes and makes case

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1 series -- I mean, case reports and small little  
2 documents and over -- potentially makes conclusions  
3 that we can't make from those level of data. So,  
4 this is a potential overstatement.

5 Q. Okay. But, Doctor, if you haven't read  
6 it, how do you know whether it's an overstatement,  
7 an understatement or a neutral statement?

8 A. Well, we read the part together talking  
9 about complications from TVT-O. Those are -- I  
10 know like those are case reports.

11 Q. At what point did you take a look at  
12 what Dr. Blaivas cited and go back to the reference  
13 list, see what those articles were and go through  
14 it? You didn't do that.

15 A. I didn't have to.

16 Q. So, you -- you know what? Maybe this  
17 is -- maybe this is just your position and we  
18 can...

19 You don't believe that in order to  
20 assess whether there is an overstatement,  
21 understatement or neutral statement of a position  
22 in this paper, you don't believe you have to read  
23 it in order to do that?

24 MR. SNELL: Form, misstates.

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1 BY THE WITNESS:

2 A. As we've discussed, I think that the  
3 level of that kind of a paper is one or a group of  
4 people sifting through the literature in a  
5 non-systematic method, using a non-systematic  
6 methodology and coming up with conclusions. That  
7 is not what happens when you do a systematic  
8 review.

9 BY MS. FITZPATRICK:

10 Q. Okay. But I'm not talking about a  
11 systematic review. I'm talking about a position  
12 statement. This is not a systematic review of the  
13 literature, correct?

14 A. No. It is --

15 Q. And in fact --

16 A. It relies upon Level 1 data almost  
17 exclusively. So, it's not commenting on things  
18 that are kind of out there that we don't really  
19 know. So...

20 Q. And your assumption is that that's what  
21 Dr. Blaivas' paper does even though you haven't  
22 read it?

23 MR. SNELL: Objection; misstates.

24 BY THE WITNESS:

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1           **A.**     I read a portion of it and I know that  
2     that's what it does.

3     BY MS. FITZPATRICK:

4           **Q.**     You've read about four sentences with  
5     me, Dr. Kenton. Is that -- when you read an  
6     article, do you think you can read four sentences  
7     and make a determination? Is that how you do it?

8           **A.**     I can make a determination of the  
9     overstatement of the complications, yeah, because  
10    that's what we read.

11          **Q.**     Is this how you prepared your expert  
12    report? Did you read just a couple sentences from  
13    an article or a document, make an assumption about  
14    it, put it in your expert report and move on?

15          **A.**     I didn't have to make an assumption  
16    about this. I know the data around and what's been  
17    published around complications of infection  
18    around --

19          **Q.**     Tell me what the overstatement is. Open  
20    the paper and tell me what the overstatement is.

21          **A.**     I'm trying to find the part that we were  
22    reading.

23          **Q.**     I'll help you out. It's page 7.

24          **A.**     So, "Thigh abscesses, a complication

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1 unique to the TOT sling, have been reported in the  
2 past decade."

3 Q. So, is that untrue?

4 A. It's not untrue.

5 Q. Is that an overstatement?

6 A. But I think that to take -- the reason  
7 that that doesn't hit the peer-reviewed like  
8 systematic review of literature is because you  
9 can't take an isolated case of anything. I mean,  
10 people die walking across the street.

11 So, when you have an isolated rare event  
12 and it gets reported as a case report, it's  
13 important to know, it informs things. But it is  
14 not going to be like -- you're not going to make a  
15 determination on how you treat millions based on an  
16 isolated case report.

17 Q. Okay.

18 A. Or several.

19 Q. You said -- you used the word  
20 "overstatement."

21 Is it incorrect, is it an overstatement  
22 in any way to say "Thigh abscesses, a complication  
23 unique to the TOT sling approach, have been  
24 reported in the past decade"? Is that an

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1     overstatement?

2             A.     The statement alone isn't an  
3     overstatement.

4             Q.     Okay.

5             A.     The interpretation that one shouldn't  
6     use midurethral slings based on case reports I  
7     think would be an overstatement.

8             Q.     Show me where that is. Show me where  
9     that says shouldn't use -- you shouldn't use  
10    midurethral slings based on case reports. Show me  
11    where Dr. Blaivas says that in this paper.

12            A.     Perhaps, perhaps he doesn't.

13            Q.     Okay. So you don't actually know what  
14    he says in this paper because you haven't read it.

15            MR. SNELL: Form, asked and answered.

16    BY MS. FITZPATRICK:

17            Q.     Is that right?

18            A.     We read parts of it together. As I've  
19    indicated, this isn't the level of data in papers  
20    that I base my opinions on.

21            Q.     Okay. So, let me ask you a  
22    hypothetical.

23            A.     So, I never would have brought this to  
24    the table.

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1           Q.     I come in to see you for stress urinary  
2     incontinence. Okay. And you talk to me about  
3     putting in a transobturator sling. Correct?

4           A.     If you had certain criteria, yes.

5           Q.     Sure. Let's assume I fit whatever the  
6     criteria it is for you.

7                     And you know that thigh abscesses have  
8     been reported in the literature associated with the  
9     transobturator sling procedure. Correct? You have  
10    that knowledge?

11          A.     Definitely.

12          Q.     Are you going to tell me about that or  
13    are you not going to tell me about it because it's  
14    not Level 1 evidence?

15          A.     Of course I'm going to tell you that you  
16    have a risk of infection and -- I'm going to go  
17    through the whole nine yards.

18          Q.     And are you going to tell me that I have  
19    a risk of a thigh abscess as part of the infection  
20    because you know that it's been reported in the  
21    literature?

22          A.     Sure. And you have a risk of a  
23    abdominal abscess or retropubic abscess if I do a  
24    retropubic or a pubovaginal sling.

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1           Q.     So, it's important enough information  
2     that you would tell a patient because a patient has  
3     a right to know that a thigh abscess can occur with  
4     the placement of a transobturator sling, correct?

5           A.     Correct.

6           Q.     So, what's wrong with Dr. Blaivas  
7     telling doctors that thigh abscesses, a  
8     complication unique to the transobturator sling  
9     approach, have been reported in the past decade?  
10    Isn't that important information for a doctor to  
11    know?

12          A.     I would hope that the doctors were  
13    putting midurethral sling or midurethral slings in  
14    would have known about those case reports on their  
15    own, but -- sure.

16          Q.     But don't you think -- there is 2,000 --  
17    what, 2,000 plus articles that are out there that  
18    deal with midurethral slings, right?

19          A.     Yes, more than any other incontinence  
20    procedure we have.

21          Q.     Right. But very, very few of those are  
22    actually the Level 1 evidence that you rely on for  
23    your decisions, correct?

24          A.     Correct.

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1           Q.     But the rest of those articles provide  
2     some information to physicians such as yourself,  
3     correct?

4           A.     Correct.

5           Q.     And you don't suggest that a physician  
6     who implants TVTs is responsible for going out  
7     every day into the medical literature and every day  
8     reading over those 2,000 articles, correct?

9           A.     Correct.

10          Q.     And, so, peer-reviewed articles like  
11     Dr. Blaivas' synthesize what's out there in the  
12     medical literature, correct?

13          MR. SNELL:   Object to the foundation on what  
14     he actually did.   Synthesis.

15          MS. FITZPATRICK:   She seems to know what he  
16     did.

17          MR. SNELL:   Well, you are positing that he  
18     synthesized it when you know I have deposed him on  
19     what all he left out of this.   So, that's my  
20     foundation about what he supposedly did.

21          MS. FITZPATRICK:   Well, I don't believe you're  
22     a doctor, Burt.   I don't believe you've done  
23     medical research.

24          THE WITNESS:   Let's not go there again.

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1 MR. SNELL: It's okay. I'm just making my  
2 objection. That's fine.

3 MS. FITZPATRICK: No, you're not. You're  
4 making an improper objection and you know that.

5 MR. SNELL: Absolutely not. You've made  
6 representations about what he did in your question,  
7 and I'm allowed to object on the foundation on  
8 that. That's the only reason I made this.

9 MS. FITZPATRICK: No, you're testifying, Burt,  
10 and cut it out.

11 MR. SNELL: I'm not.

12 BY MS. FITZPATRICK:

13 Q. Please answer the question, Dr. Kenton.

14 A. So, this paper where he reports a TOT  
15 abscess, and he is just talking about the  
16 complications of midurethral sling, is not -- as I  
17 said, it can be on either side.

18 This is not where I personally go to  
19 rely on somebody else's synthesis of the literature  
20 that isn't comparative. There is no comparators in  
21 here. So, there is a TOT abscess.

22 Do they talk about the complications of  
23 a higher rate of bowel injury with a Burch or like  
24 abdominal wall abscesses with a sling?

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1           Q.     Maybe if -- maybe if you read the  
2     article you'd know.

3           A.     Perhaps I would. But as I said, this  
4     isn't the level of evidence I rely upon.

5           Q.     But this AUGS-SUFU statement --

6           A.     I didn't say it's the level of evidence  
7     I rely on.

8           Q.     So, you would not rely on the  
9     AUGS-SUFU statement --

10          A.     Do I think it's a reliable statement?  
11     They're not overstating anything.

12          Q.     But you don't rely on the AUGS-SUFU  
13     statement for reaching your conclusions in this  
14     particular case, correct? That's --

15          A.     No.

16          Q.     This is not the evidence that you have  
17     relied on?

18          A.     I think one of the very first things I  
19     testified to is I rely on my own review of the  
20     peer-reviewed literature.

21          Q.     And it's not the AUGS-SUFU statement,  
22     correct?

23          A.     Do I rely on it? I -- I think it's  
24     useful, but it's not the thing that -- this isn't

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1 what made me decide to keep using midurethral  
2 slings.

3 Q. Okay. Let's go back to where we  
4 started. You wanted to look at Doctor -- at the  
5 Schimpf article.

6 I'm looking on the section on  
7 pubovaginal slings versus midurethral sling and  
8 what I'm trying to understand is -- well, let me  
9 ask this.

10 Do you believe that the TVT Retropubic  
11 is a safer alternative to an autologous fascial  
12 sling?

13 A. I do. I think it has different risks  
14 and benefits.

15 Q. Is it a safer procedure than the  
16 autologous -- is it a safer alternative to the  
17 autologous fascial sling?

18 A. As I said, I think that as with all  
19 procedures, there is a different risk/benefit  
20 profile. I mean, I think I testified yesterday  
21 that I discuss those risks and I help each  
22 individual woman decide which risk/benefit profile  
23 she is trying to take.

24 Q. Okay. And what I'm trying to

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1 the video record.

2 BY MS. FITZPATRICK:

3 Q. Now, Dr. Kenton, one of the criticisms  
4 that you have of Dr. Blaivas' paper is that he  
5 includes case reports and non-Level 1 evidence in  
6 it, correct?

7 A. So, I think that I would like to  
8 clarify. I'm not criticizing his paper. You asked  
9 me if I read it. That's not the level -- that's  
10 not the type of article I read in making a  
11 decision.

12 Q. Okay. But, Dr. Kenton, we spent quite a  
13 bit of time on this record with you saying that you  
14 believed that Dr. Blaivas was looking at and  
15 included literature that was low-level literature,  
16 correct?

17 A. I think that you're making it personal  
18 that it's something about Dr. Blaivas. I've said  
19 on numerous occasions that type of document is not  
20 what I rely upon because they include not all  
21 high-level evidence. That's why they designed  
22 systematic reviews and meta-analyses, and I've said  
23 that repeatedly.

24 Q. Okay. So, you're not critical, then, of

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1 the literature that Dr. Blaivas has relied on, is  
2 that right?

3 MR. SNELL: Form.

4 BY MS. FITZPATRICK:

5 Q. It seemed like for about an hour you  
6 were very critical of what you believed he had or  
7 hadn't relied on and the quality of that review.

8 MR. SNELL: Form, asked and answered.

9 BY THE WITNESS:

10 A. I would say that what I was saying, you  
11 were accusing me of not reading this. I explained  
12 the reason I don't read these level of data,  
13 regardless of what side they're on, is because  
14 they're not a statistical accumulation of  
15 high-quality data.

16 And then we went into like going through  
17 what are the limitations with these type of data  
18 compared to something like a systematic review or  
19 meta-analysis.

20 MS. FITZPATRICK: Okay. If we can mark this  
21 as Exhibit 12. I'm sorry. The first one has a  
22 highlight on it.

23 What are we at?

24 THE REPORTER: 13.

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1 systematic or comprehensive review of the  
2 literature on midurethral slings, would that change  
3 your opinion as to its reliability?

4 MR. SNELL: Foundation.

5 BY THE WITNESS:

6 A. I -- it's clearly not based -- it's not  
7 a systematic review. I mean, it's a -- it's a  
8 review of the literature similar to the one that we  
9 talked about with Dr. Blaivas where they reviewed  
10 some literature and they offered their position on  
11 it.

12 BY MS. FITZPATRICK:

13 Q. How do you know it's the same as the one  
14 done by Dr. Blaivas?

15 A. It's the same level of evidence when you  
16 talk about scientific evidence.

17 Q. Fine. You consider them to be --

18 A. I don't know how they -- how either of  
19 them went about their processes.

20 Q. Okay. That's what I wanted to get to.

21 So, what you're saying when you say  
22 they're the same, it's the same level of evidence  
23 from Dr. Blaivas' paper to the SUFU-AUGS statement  
24 in your opinion but you're not commenting on how

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1 comprehensive the literature reviews for either one  
2 were, correct?

3 MR. SNELL: Form.

4 BY THE WITNESS:

5 A. I think the -- I would comment based on  
6 the data lists that they are -- they are different.

7 BY MS. FITZPATRICK:

8 Q. Okay. And based on just the data lists,  
9 you'll agree that Dr. Blaivas' is more  
10 comprehensive, correct, because he cites almost 400  
11 articles as opposed to 11?

12 A. I think that more comprehensive does not  
13 mean better. For instance, if each of these  
14 individual randomized controlled trials that you  
15 just pointed out with 20 or 40 people in them were  
16 cited and taken as an isolated paper on its own,  
17 they're meaningless.

18 So, it doesn't help to have that added  
19 to the literature until you compile them together.

20 Q. Then why did you include in your  
21 references opinions and case reports if those are  
22 meaningless?

23 A. I didn't say. These are randomized  
24 controlled trials that you handed me that are

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1     tenderness in a particular area of the vagina that  
2     when you touch it, it hurts like heck.

3           A.     That's a trigger point. That could be  
4     muscular.

5           Q.     Okay.

6           A.     It's hard to -- I will -- it's hard to  
7     distinguish if it's the foreign body or it is the  
8     muscle that's causing that pinpoint tenderness  
9     frequently.

10          Q.     So, if you palpate suburethrally where  
11     the mesh is and it hurts a lot, right in that area,  
12     how do you as a doctor go about figuring out  
13     whether it's related to the mesh or whether it's a  
14     pelvic floor muscle dysfunction somewhere else?

15          A.     If -- occasionally if it looks like the  
16     mesh is exposed or there is something that makes me  
17     more suspicious for mesh, I go on the mesh.

18                   Otherwise, I usually start with physical  
19     therapy and with a good, well-trained physical  
20     therapist and see if they improve.

21          Q.     Okay. What if the mesh isn't exposed?

22          A.     With midurethral slings, typically, if  
23     it's palpate tenderness under the urethra, as I  
24     said, and I can -- you know, levators and muscles

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1 pain" used in the medical literature in association  
2 with a TVT sling?

3 A. I've seen it used in association with.  
4 But chronic pain actually, chronic pelvic pain has  
5 a very discrete diagnosis -- I mean definition.  
6 But, yes, I've seen that terminology used.

7 Q. Okay. The chronic pelvic pain that you  
8 talk about that has a very discrete diagnosis, have  
9 you seen that reported in the medical literature  
10 associated with the TVT?

11 A. Yes.

12 Q. The chronic pelvic pain -- and is that  
13 Level 1 evidence that you have seen?

14 A. Yeah, it does fall into some of the  
15 randomized controlled trial data.

16 Q. Okay. Is chronic pain associated with  
17 the autologous fascial sling reported in the  
18 medical literature?

19 A. It is.

20 Q. In what level?

21 A. Level 1.

22 Q. And where is that reported?

23 A. There is pelvic pain reported in the  
24 SISTER trial as well.

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1                   No. 21, Ethicon document, "All  
2                   active contracts for 2008 through  
3                   Nov. 19, 2008"; Bates No.  
4                   Eth.Mesh.05013617, and No. 22,  
5                   11/11/2010 Ethicon document re  
6                   contracts; no Bates numbers.)

7           MR. SNELL: That's it.

8           MS. FITZPATRICK: Are you done testifying,  
9   Mr. Snell?

10          MR. SNELL: I'm not testifying. I was  
11   questioning.

12                   FURTHER EXAMINATION

13   BY MS. FITZPATRICK:

14          Q.     Turn to page 11 of your report.  
15                   You don't cite this 2006 study. What is  
16   it?

17          A.     What do you mean I don't cite it?

18          Q.     I don't see a footnote that tells me  
19   what study --

20          A.     I didn't put the reference in?

21          Q.     No. What study is it?

22          A.     I mean, if I did have the reference,  
23   I'll have to go back and pull it from my file.

24          Q.     Do you believe that it's -- it would be

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1 appropriate for me to use data on complication  
2 rates related to the ObTape and as a basis for what  
3 I can expect out of complications from a TVT  
4 device?

5 A. I believe that ObTape has higher erosion  
6 rates than TVT.

7 Q. Okay. So, why would you use a paper  
8 that's comparing the erosion rates of an ObTape  
9 laser-cut to a TVT-O mechanical-cut to support your  
10 opinion that there is no difference between the  
11 TVT Retropubic mechanically-cut and the TVT  
12 laser-cut?

13 A. Because there are very few data about  
14 actually mechanically-cut versus laser-cut, and  
15 that's about as good as the data is going to get.

16 Q. That's the best you can get. But you  
17 agree with me, that's not a very good comparison,  
18 is it?

19 A. It's not any better than the -- it's --  
20 to me it's not better or worse than the theories  
21 that an engineer who has never touched a patient  
22 has.

23 Q. Is that sufficient data for you as a  
24 surgeon to rely on to make the determination that

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1 is a difference, and there is a propensity of data  
2 to support the mechanically-cut TVT is safe.

3 BY MS. FITZPATRICK:

4 Q. Okay. Do you believe that a study  
5 comparing an ObTape laser-cut group to a  
6 mechanically-cut TVT-O group is an appropriate  
7 comparator or data to use when trying to determine  
8 the clinical performance differences between the  
9 TVT-R mechanical-cut and the TVT-R laser-cut?

10 MR. SNELL: Objection; form, asked and  
11 answered.

12 BY THE WITNESS:

13 A. I don't believe that there are any  
14 compelling data to use to compare those two.

15 BY MS. FITZPATRICK:

16 Q. Okay. Including this 2006 study that  
17 you cite, correct?

18 A. Correct. It's the only thing that's out  
19 there --

20 Q. Thank you.

21 A. -- which is why I included it.

22 MS. FITZPATRICK: Nothing further.

23 THE VIDEOGRAPHER: Okay.

24 MR. SNELL: That's it. Thank you.